

In re: Application of: HARTMANN et al.
Application No.: 09/990,718
Examiner: Nguyen, B. T. L.

REMARKS

This response is filed with a petition for a three-month retroactive extension of time and with an appropriate fee.

Claims 1-7 and 10-22 were pending in the present application at the time of the Office Action. Claims 1-3, 5-7, 10 and 12-16 have been amended to recite a "single zone flow lateral flow device including a substrate having a first end, and a second end, said first end having thereon a billfish specific antigen-containing sample that has been immobilized" and a "solution comprising billfish specific antibody that flows laterally from said second end to said first end of said device and specifically binds to said billfish-specific antigen." Support for the amendments can be throughout the specification (See for example, page 18, lines 1 through 20). Claims 4 and 11 have been cancelled. No new matter is added by virtue of these amendments and their entry is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103.

Claims 1-7 and 10-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rossi *et al.*, (Hybridoma, 11(3):333-338, 1992) in view of May (GB 2,204,398).

Applicants respectfully disagree and traverse the rejection. However, before addressing the claim rejections, Applicants will first review the claimed invention as now recited in amended claim 1. Amended claim 1 recites an immunoassay device for identifying the presence of tissue from a particular species of billfish in a test sample, comprising a single zone lateral flow device. The device includes a substrate having a first end, and a second end, the first end having thereon a billfish specific antigen-containing sample that has been immobilized. The said second end has structure for receiving a solution including a billfish specific antibody that flows laterally from the second end to the first end of the device and specifically binds to the billfish-specific antigen.

Regarding Rossi, the Examiner has already acknowledged that Rossi which Rossi discloses an indirect enzyme-linked plate assay, does not disclose a lateral flow device or

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other claimed inventive features. See Office Action, on page 2, second full paragraph copied below:

Rossi differs from the instant invention in failing to teach a lateral flow device using nitrocellulose and various reagents that are conventional in a lateral flow assay device such as gold sol label.

May does not up for the deficiencies of Rossi. In contrast to the instant invention which recites a single zone assay device, May discloses a **two zone** detection assay device. The two zones are "spatially distinct," see for example May, page 3, lines 28-31, and require two different antibodies. Moreover, May uses bound antibodies, rather than Applicants' claimed bound antigen-containing sample. In May, The first antibody is a labeled antibody which is immobilized in the first zone. The second zone requires use of a second unlabeled antibody which is "permanently immobilized." (See, for example, page 3, line 13). The first antibody is allegedly mobile when a moist sample is added and the second antibody is allegedly permanently immobilized. Each antibody is directed to different epitopes. Therefore, May discloses a two zone assay device having immobilized antibodies, where two different antibodies are disposed in the two different zones.

May also teaches away from the claimed invention. The Office Action states on page 3, first paragraph, "May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic soles and colored latex particles." However, as discussed *supra*, these antibodies must "become mobile" when in a moist state and require a second permanently immobilized antibody to detect the antigen. May, therefore, teaches away from using the claimed device wherein the sample is immobilized and a billfish specific antibody is added for detection of antigen. One of ordinary skill in the art is aware that different conditions (e.g. type of solution, pH, salt, etc) affect both the conformation and binding abilities of antibody including the stability of the bond between the antibody and the label. Especially so, since a lateral flow antibody based assay for detecting proteins from fish species caught in the wild would require coupling gold particles to either the antibody or the fish albumin and determining

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if conjugation affects their ability to interact. May does not disclose or suggest how any of the antibodies would be suitable for use in a lateral flow immunoassay device.

In contrast, amended claim 1 recites a single zone lateral flow device having a billfish specific **antigen-containing sample** immobilized on a substrate and a solution including a billfish specific antibody that flows laterally from the second end to said first end of the device and specifically binds to the billfish-specific antigen. May fails to teach or suggest such a device, whether alone or in combination with Rossi. Therefore, Applicants submit that claims 1-3, 5-7 and 10, 12-22, are patentable over the cited art.

Applicants would also like to point out other claimed patentable embodiments of the invention. For example, claim 13 is directed to detection of a billfish specific antigen in the lateral flow immunoassay device based on a **gold**-conjugated monoclonal antibody. The novelty and importance of the instant invention is that the gold-conjugated monoclonal antibody detects bill-fish specific antigens among closely-related species of fish. (See for example, page 8, lines 19-20). Rossi *et al.* in view of May *et al.* do not teach or suggest a lateral flow device containing an antibody solution for detection of billfish antigen. Rossi *et al.* in view of May *et al.* are silent regarding the use of gold-conjugated antibodies that are specific for billfish antigens in a lateral flow immunoassay device.

Claim 16 and its respective dependent claims are patentable for the same reasons noted above with respect to claim 1.

CONCLUSION

Applicants respectfully request entry of the foregoing remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 1-3, 5-7 and 10, 12-22 define patentable subject matter and is in condition for allowance. Accordingly, Applicants respectfully request allowance of all pending claims.

The foregoing is submitted as a full and complete Response to the Final Office Action mailed July 29, 2004, and early and favorable consideration of the claims is requested.

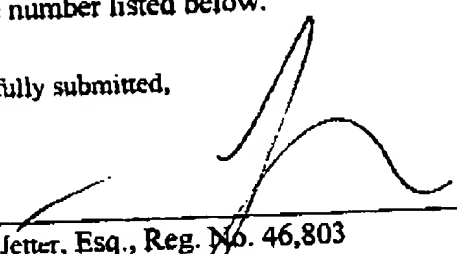
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The Director for Patents is hereby authorized to charge any deficiency in fees due or credit an excess in fees with the filing of the papers submitted herein during prosecution of this application to Deposit Account No. 50-0951.

Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is respectfully requested to contact Applicant's representative at the telephone number listed below.

Respectfully submitted,

Dated: 1/28/05


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